K070979
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ICU MEDICAL INC.
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Tracy S. Best, Sr. Regulatory Affairs Specialist
Preparation Date: June 05, 2007

SEP 19 2007

Special 510(K) – Summary for the:

Trade Name: Pull Tab Squeeze Flush

Common Name: Continuous flush catheter

Classification Name: Continuous flush catheter, 21 CFR 870.1210, Class II Device

Legally Marketed Predicate Devices for Substantial Equivalence:

*Pre-Amendment Device – Intraflo® – Sorenson Medical – (now ICU Medical Inc.)

Rationale for SE:

The Intraflo® is a pre-amendment device developed by Sorenson Medical and subsequently now owned by ICU Medical, Inc. The Intraflo® is a device that has been utilized since 1976 for use as a continuous flush device that incorporates a pull tab which, when pulled sends a square wave to calibrate the cardiac monitoring devices.

Description of Submitted Device:

The Pull Tab Squeeze Flush (PTSF) is a continuous flush device that contains an orifice used to provide a continuous fixed flow rate of IV solution to facilitate arterial pressure monitoring and to maintain patency.

The device also includes a mechanism which, when activated, provides a fast flush flow rate used to prime the device and monitoring kit. The fast flush rate continues to flow as long as the fast flush mechanism is mechanically activated. The fast flush also provides a means to flush the monitoring kit following blood sampling and to allow measurement of the system's dynamic response. The PTSF device is capable of creating a square wave signal in the pressure line to the transducer whenever the fast flush mechanism is activated and quickly released or the tab is squeezed quickly and released quickly.

The device consists of rigid transparent lure connections for adapting to standard male and/or female lures, a flow restrictor, and a fast flush mechanism. It is available in two nominal flow rates, 3ml/hr and 30 ml/hr. The fast flush mechanism clip may be removed to enable patient mounting of the device.

Intended Uses of the Pull Tab Squeeze Flush:

The Pull Tab Squeeze Flush (PTFS) an attachment to a catheter – transducer system that permits continuous intravascular flushing at a slow infusion rate for the purpose of eliminating clotting, back-leakage and waveform damping.

The PTSF is currently made in four models - 3 ml and 30 ml each with or without tee connector.

Technological Characteristics and Substantial Equivalence:

Similarities:

1. The current and proposed devices have the same intended use.
2. The current and proposed devices have the same indications for use.
3. The current and proposed devices contain the components made from the same materials with the one exception noted below.

Differences:

1. The proposed device contains an external squeeze clip (non-patient contacting) to activate the fast flush mechanism in addition to the existing pull tab.
2. The proposed device will use a different material vendor for the silastic sleeve which ICU uses on other disposable devices we sell.

Safety and Performance:

ICU Medical Intraflo has been sold for more than three decades and is proven technology. No additional safety and performance testing is necessary. ICU Medical's Sterility Assurance Level, (SAL) has an established history of meeting the 10^{-6} level. The devices are packaged in peel pouches and they ensure conformity with ISO 10993, including minimizing residual gases.

Performance Standards:

No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for Continuous flush catheters. Continuous flush catheters are regulated within 21 CFR 870.1210.

Conclusion:

The materials, performance, and operational features of both the submitted device and the pre-amendment device are substantially equivalent to one another and are safe and effective for their intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 19 2007

ICU Medical, Inc.
c/o Mr. Tracy Best
Senior Regulatory Affairs Specialist
4455 Atherton Drive
Salt Lake City, UT 84123

Re: K070979
Pull Tab Squeeze Flush
Regulation Number: 21 CFR 870.1210
Regulation Name: Continuous Flush Catheter
Regulatory Class: Class II
Product Code: KRA
Dated: August 22, 2007
Received: August 23, 2007

Dear Mr. Best:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K070979**

Device Name: **Pull Tab Squeeze Flush (PTSF)**

Indications for Use:

The Pull Tab Squeeze Flush (PTFS) an attachment to a catheter – transducer system that permits continuous intravascular flushing at a slow infusion rate for the purpose of eliminating clotting, back-leakage and waveform damping.

The PTSF is currently made in four models - 3 ml and 30 ml each with or without tee connector.

Prescription Use ___XX___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Andrew Bram for BDZ

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K070979